PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 4919FAR	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/AU2004/000783	International filing date *(day/month/year)* 11 June 2004	Priority date *(day/month/year)* 13 June 2003

International Patent Classification (IPC) or national classification and IPC

Int. Cl.[7] A63B 71/08

Applicant

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1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 3 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. [X] *(sent to the applicant and to the International Bureau)* a total of 9 sheets, as follows:
      - [X] sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      - [ ] sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. [ ] *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:

[X]	Box No. I	Basis of the report
[ ]	Box No. II	Priority
[ ]	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
[ ]	Box No. IV	Lack of unity of invention
[X]	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
[ ]	Box No. VI	Certain documents cited
[ ]	Box No. VII	Certain defects in the international application
[ ]	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of the report
4 November 2004	21 September 2005
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer J.W. THOMSON Telephone No. (02) 6283 2214

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/AU2004/000783

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:

☐ international search (under Rules 12.3 and 23.1 (b))

☐ publication of the international application (under Rule 12.4)

☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

☐ the international application as originally filed/furnished

☒ the description:

pages **1 – 4, 7 - 19** as originally filed/furnished
pages* **5, 6** received by this Authority on **6 September 2005** with the letter of **6 September 2005**
pages* received by this Authority on with the letter of

☒ the claims:

pages as originally filed/furnished
pages* as amended (together with any statement) under Article 19
pages* **20 – 23, 26** received by this Authority on **28 April 2005** with the letter of **28 April 2005**
pages* **24, 25** received by this Authority on **6 September 2005** with the letter of **6 September 2005**

☒ the drawings:

pages **1 - 16** as originally filed/furnished
pages* received by this Authority on with the letter of
pages* received by this Authority on with the letter of

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages
☐ the claims, Nos.
☐ the drawings, sheets/figs
☐ the sequence listing (*specify*):
☐ any table(s) related to the sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages
☐ the claims, Nos.
☐ the drawings, sheets/figs
☐ the sequence listing (*specify*):
☐ any table(s) related to the sequence listing (*specify*):

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1 - 46	YES
	Claims	NO
Inventive step (IS)	Claims 1 - 46	YES
	Claims	NO
Industrial applicability (IA)	Claims 1 - 46	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

WO 1995/023013 (WESTERMAN)

US 5339832 (KITTELSEN et al)

US 6584978 (BRETT et al)

WO 2000/035369 (FARRELL)

Novelty and Inventive Step – Claims 1 to 46

These citations do not disclose the invention as defined in claims 1 to 46. The differences between these disclosures and the claimed invention involve an inventive step. Claims 1 to 46 are therefore novel and involve an inventive step.

Preferably the shock absorption means takes the form of at least one open channel defined in each side of the generally U-shaped form of the base member in or near terminal ends and/or at least one open channel arranged in a front section of the base member.

The frontal open channel may have a length lying in the range 2-10mm, preferably 4-8mm.

Preferably the side open channels are arranged in or near the terminal ends of the generally U-shaped form of the base member and have a length of between 10-20mm.

The base member may comprise an inner flange and an outer flange interconnected by a web which together defines the channel/s.

At least some of the openings or channels may be defined in the outer flange. The openings or channels may be defined in the outer flange below the general level of the web and on the other side of the flange from the teeth engaging element for the upper arch.

The outer flange may have a skirt or extension that projects downwardly below the web and the channels or openings may be defined in the skirt or extension of the base member that is below the web.

One or more openings may also be defined in the inner flange below the general level of the web. Further the inner flange may have a skirt or extension that projects downwardly below the web and the channels or openings may be defined in the skirt or extension of the base member that is below the web.

In some forms the openings and/or channels may be defined in both the inner and outer flanges. In particular the side openings or channels may be defined in both the inner and outer flanges. Further the front channel or channels may be defined in the outer flange, eg below the web.

Each of the channels may be positioned in a lower region of the base member, eg closely spaced or adjacent to the lower edge of the base member. This positioning in the lower region of the base member assists in absorbing energy from blows transmitted in an upward direction to the guard.

The appliance may have a plurality of said channels defined in the base member along the length of the base member. For example the appliance may have at least two channels defined in each arm of the base member, apart from the frontal channels. Further the appliance may define two frontal channels positioned on either side of the mid line of the base member, closely spaced from each other.

Thus the appliance may define two frontal channels and then two further channels on each arm positioned rearwardly of the frontal channels.

The length and volume defined by the channels may decrease in a direction rearwardly from the front of the member. For example the rear channels may have a substantially smaller length than the frontal channels.

At least some of the channels may have a length that is more than twice as great as their height. Preferably at least some of the channels have a length that is more than three times their height.

CLAIMS:

1. An oral appliance for placing in a mouth of a user, the appliance including:

- a base member having a generally U-shaped form corresponding to the outline of a jaw of a user, the base member defining at least one channel within which an upper or lower row of teeth of a user can be received,

- a teeth engaging element, associated with each channel, being made of a material able to be user conformed or user moulded to suit the individual mouth of the user wherein the base member has a greater rigidity than the teeth engaging element, and;

- shock absorption means for absorbing impact shock, the shock absorption means comprising one or more air channels or spacings defined in the base member.

2. Oral appliance according to claim 1, wherein the shock absorption means comprises one or more open air channels defined in the base member.

3. Oral appliance according to claim 1, wherein the air channels extend from an outer face of the base member, through the body thereof to an inner face of the base member.

4. Oral appliance according to claim 3, wherein the shock absorption means take the form of channels with open sides arranged in or near terminal ends of the generally U shaped form of the base member.

5. Oral appliance according to claim 4, further including at least one frontal open channel arranged in a front section of the base member.

6. Oral appliance according to claim 4, wherein the side open channels have a height in the range of 0.5-10mm and length lying in the range of 0.5-30mm.

7. Oral appliance according to claim 6, wherein the side open channels that are positioned proximate to the terminal ends of the generally U shaped form of the base member have a length lying in the range 10-20mm.

8. Oral appliance according to claim 5, wherein the frontal open channel of the base member has a length lying in the range 2-10mm.

9. Oral appliance according to claim 1, wherein the teeth engaging element is made of a continuous layer of thermoplastic material that encapsulates the base member to firmly and securely mount the layer of thermoplastic material on the base member.

10. Oral appliance according to claim 9, wherein the continuous layer of thermoplastics material substantially covers the complete surface area of the base member.

11. Oral appliance according to claim 9, wherein the layer of thermoplastic material defines one or more openings which correspond with at least one or more of the open channels arranged in the base member.

12. Oral appliance according to claim 9, wherein the layer of thermoplastic material extends across and covers the one or more openings which correspond with the at least one or more channels arranged in the base member and closes off the interior space defined by the channels.

13. Oral appliance according to claim 9, wherein the layer of thermoplastic material is EVA (ethylvinylacetate) which softens at a temperature of 90°C - 95°C.

14. Oral appliance according to claim 9, wherein the layer of thermoplastic material forming the teeth engaging elements has a thickness of 1mm – 3mm.

15. Oral appliance according to claim 1, wherein the base member is formed from a rigid plastics material, which is not user conformable or mouldable in boiling water.

16. Oral appliance according to claim 15, wherein the rigid plastics material comprises a non-thermoplastic material either alone or in combination with another plastics material.

17. Oral appliance according to claim 16, wherein the non-thermoplastic material comprises polyethylene, polyurethane, polypropylene or santoprine.

18. Oral appliance according to claim 16, wherein the other plastics material is a thermoplastic material and the thermoplastic material is 10% or less by weight of the base member.

19. Oral appliance according to claim 18, wherein the base member comprises 3-8% by weight of thermoplastic material that is EVA and the balance is polyethylene.

20. Oral appliance according to claim 18, wherein the base member comprises 4-6% by weight of thermoplastic material that is EVA and the balance is polyethylene.

21. Oral appliance according to claim 17, wherein the non-thermoplastic material comprises polyethylene on its own.

22. Oral appliance according to claim 1 wherein the base member has inner and outer flanges interconnected by a web which collectively define upper and lower channels within which the upper and lower rows of teeth of the user are receivable, wherein an upper teeth engaging element is receivable in the upper channel and a lower teeth engaging element is receivable in the lower channel.

23. Oral appliance according to claim 1 further including a tongue tag on the inner flange of the base member, the tongue tag being substantially centrally positioned for correctly positioning the tongue of a user during use, and a cut-out defined in the outer flange of the base member for allowing the appliance to adapt to varying arch sizes, and breathing apertures defined in the base member for facilitating breathing by a user when wearing the appliance.

24. Oral appliance according to claim 1 further including locating means for correctly locating and positioning the jaws in the teeth engaging element during fitting of the oral appliance.

25. Oral appliance according to claim 24, wherein the locating means comprise a brace arranged externally on the teeth engaging element.

26. Oral appliance according to claim 24, wherein the brace comprises rubber.

27. An oral appliance for placing in a mouth of a user, the appliance including:

- a base member having a generally U-shaped form corresponding to the outline of a jaw of a user, the base member defining at least one channel within which an upper or lower row of teeth of a user can be received, and wherein the base member is made of polyethylene with less than 10 % by weight of a thermoplastics material

- a teeth engaging element mounted over the base member in each channel made of a thermoplastics material that is able to be user conformed or user moulded to suit the individual mouth of the user.

28. An oral appliance according to claim 27, wherein the base member is made of polyethylene with 3-8% by weight of thermoplastics material.

29. An oral appliance according to claim 27, wherein the base member is made of polyethylene with 4-6% by weight of thermoplastics material.

30. An oral appliance according to claim 27, wherein the base member is made of high density polyethylene with 4-6% by weight of thermoplastics material which is EVA and each teeth engaging element is made of EVA.

31. An oral appliance according to claim 27, wherein the base member defines only an upper channel within which upper teeth of a user are received.

32. A method of manufacturing an oral appliance for placing in the mouth of a user, the method including the steps of:

- molding a base member from plastic material in a first molding step in a first mould, the member having a generally U-shaped form corresponding to the outline of the jaw of a user and inner and outer flanges interconnected by a web which define at least one of upper and lower channels within which the corresponding rows of teeth of a user are received;

- arranging one or more spacings in the base member and;

- removing the base member from the first mould and placing it in a second mould having a larger mould cavity and moulding a continuous layer of thermoplastic material onto the base member to form at least one of the upper and lower teeth engaging elements capable of being customised to suit the mouth of a user, the layer encasing the member to thereby firmly and securely mount the layer of thermoplastic material on the base member.

33. A method according to claim 32, wherein the continuous layer of thermoplastic material is molded substantially fully across the surface area of the base member in said second molding step.

34. A method according to claim 32, wherein the base member is injection molded from polyethylene, polyurethane, polyethylene, polypropylene or santoprine.

35. A method according to claim 32, wherein the layer of thermoplastic material is injection molded from EVA while it is locked in position in the second mould.

36. A base member for an oral appliance for placing in a mouth of a user, having a generally U-shaped form corresponding to the outline of a jaw of a user, the base member defining at least one channel within which an upper or lower row of teeth of a user can be received, the base member further comprising shock absorbing means taking the form of pre-designated compressible sections in order to substantially

absorb impact shock, each compressible section extending across the full width of the base member.

37. A base member according to claim 36 comprising a first material, preferably being polyethylene and a second material, being EVA, wherein the weight percentage of EVA in the base member preferably lies in the range 0.5-10% and is more preferably in the range 4-8%.

38. A base member according to claim 37 being at least semi-flexible and non-thermoplastic.

39. A moldable teeth engaging element for co-operation with a base member according to claim 36 for an oral appliance, the element being made of a material able to be user conformed or user molded to suit the individual mouth of the user, provided with locating means for correctly locating and positioning the jaws in the teeth engaging element.

40. A method of fitting an oral appliance, as described in claim 1 comprising the step of immersing the oral appliance in water having a temperature sufficiently high to make the teeth engaging element moldable,

- inserting the appliance into a user's mouth;
- biting into the teeth engaging element to mould the teeth engaging element to the form of the user's jaw, and thereafter allowing the teeth engaging element to harden.

41. A method for protecting teeth from impact shock comprising the step of inserting an oral appliance, fitted according to claim 40, into a user's mouth before partaking of any activity whereby use of a mouthguard is desirable.

42. A guard for placing in the mouth of a user to perform a protective function, the guard including: a base member having a generally U-shaped form corresponding to the arch of a jaw of a user having a front region extending back via two arms to a rear end, the base member defining at least an upper channel within

which the upper jaw of a user can be received; a teeth engaging element received in each said channel that is made of a material that is able to be user moulded to fit the mouth of a user, the base member including a shock absorber for absorbing energy from an impact to the guard, the shock absorber comprising at least one side opening defined in the outer flange of each said arm and a front opening defined in the outer flange of the front region.

43. A guard according to claim 42, wherein the guard defines only an upper said channel to fit over the upper arch of the use.

44. A guard according to claim 43, wherein the outer flange includes a downward extension or skirt that extends down from the web in a direction away from the upper channel and the side openings are defined in the outer flange in the flange or skirt below the web.

45. A guard according to claim 44, wherein the front opening is also defined in the outer flange below the web.

46. A guard according to claim 42, wherein each of said side and front openings is elongate with the longitudinal axis of the opening being substantially parallel to the upper channel.